

292  
1642

I hereby certify that this correspondence is being deposited with the United States Postal Service first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450 Alexandria, VA 22313-1450, on December 27, 2004

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.

By Deborah Berwick  
Deborah Berwick

Attorney Docket No. 407J-895030US  
Client Ref. No. 98-232-4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

James D. Marks, et al.

Examiner: Larry R. Helms

Application No.: 09/250,056

Art Unit: 1642

Filed: February 12, 1999

For: INTERNALIZING ErbB2  
ANTIBODIES

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR § 1.97 and  
§ 1.98

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450


Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

This IDS is being filed after the mailing date of the first Office Action and more than three months after the filing date, but prior to the Notice of Allowance or Final Office Action. Please deduct \$180.00, pursuant to 37 CFR §1.17(p), from the undersigned's Deposit Account No. 50-0893. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

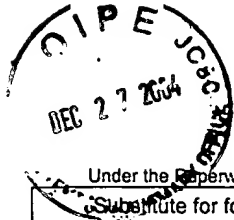
Respectfully submitted,

A handwritten signature in cursive script that reads "Angela P. Home, Ph.D.".

Angela P. Home, Ph.D.  
Reg. No. 41,079

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.  
P.O. BOX 458  
Alameda, CA 94501  
(510) 337-7871  
Fax (510) 337-7877

APH:db



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A-B/PTO

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

(use as many sheets as necessary)

## Complete if Known

Application Number	09/250,056
Filing Date	February 12, 1999
First Named Inventor	James D. Marks
Group Art Unit	1642
Examiner Name	Larry R. Helms
Attorney Docket Number	407J-895030US
Date Submitted	December 21, 2004

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, lines, Where Relevant Passages or Relevant Figures Appeal
		Number	Kind Code (if known)			
	1	5,885,793		Griffiths et al.	03-23-1999	
	2	5,733,782	A	Dorai et al.	03-31-1998	
	3	6,054,312		Larocca et al.	04-25-2000	

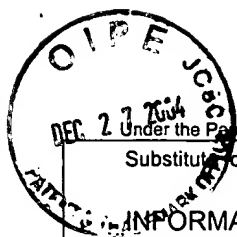
## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office	Number	Kind Code (if known)				
	4	WO	94/13804	A	Cambridge Antibody Tech	06-23-1994		
	5	WO	94/26787	A1	The Board of Trustees of the Lealand Stanford Junior University	11-24-1994		
	6	WO	99/10014	A	Selective Genetics, Inc.	03-04-1999		

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	7	ADAMS ET AL. (1998) "Increased Affinity Leads to Improved Selective Tumor Delivery of Single-Chain Fv Antibodies." <i>Cancer Research</i> 58(3): 485-490.	
	8	ANDERSEN ET AL. (1996) "A recombinant antibody with the antigen-specific, major histocompatibility complex-restricted specificity of T cells," <i>Proceedings of the National Academy of Sciences</i> 93(5): 1820-1824.	
	9	CAI ET AL. (1995) "Anti-melanoma antibodies from melanoma patients immunized with genetically modified autologous tumor cells: Selection of specific antibodies from single-chain Fv fusion phage libraries." <i>Proceedings of the National Academy of Sciences</i> 92(14): 6537-6541.	
	10	DE KRUIF ET AL. (1995) "Rapid selection of cell subpopulation-specific human monoclonal antibodies from a synthetic phage antibody library." <i>Proceedings of the National Academy of Sciences</i> 92(6): 3938-3942.	
	11	DE KRUIF ET AL. (1995) "Selection and Application of Human Single Chain Fv Antibody Fragments from a Semi-synthetic Phage Antibody Display Library with Designed CDR3 Regions." <i>Journal of Molecular Biology</i> 248(1): 97-105.	
Examiner Signature		Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A-B/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

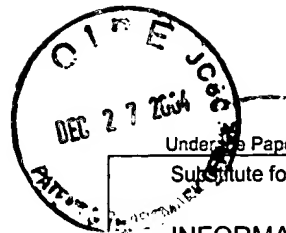
## Complete if Known

Application Number	09/250,056
Filing Date	February 12, 1999
First Named Inventor	James D. Marks
Group Art Unit	1642
Examiner Name	Larry R. Helms
Attorney Docket Number	407J-895030US
Date Submitted	December 21, 2004

12	DOUGLAS ET AL. (1996) "Targeted gene delivery by tropism-modified adenoviral vectors." <i>Nature Biotechnology</i> 14:1574-1578.
13	VAN EWIJK ET AL. (1997) "Subtractive isolation of phage-displayed single-chain antibodies to thymic stromal cells by using intact thymic fragments." <i>Proceedings of the National Academy of Sciences</i> 94: 3903-3908.
14	GRIFFITHS ET AL. (1994) "Isolation of high affinity human antibodies directly from large synthetic repertoires." <i>The EMBO Journal</i> 13(14): 3245-3260.
15	HUDZIAK ET AL. (1989) "p185 <sup>HER2</sup> Monoclonal Antibody has Antiproliferative Effects in vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor." <i>Molecular and Cellular Biology</i> 9(3): 1165-1172.
16	KASAHARA ET AL. (1994) "Tissue-Specific Targeting of Retroviral Vectors Through Ligand-Receptors Interactions." <i>Science</i> 266: 1373-1376.
17	LEWIS ET AL. (1993) "Differential responses of human tumor cell lines to anti-p185 <sup>HER2</sup> monoclonal antibodies." <i>Cancer, Immunology, Immunotherapy</i> 37(4): 255-263.
18	MARKS ET AL. (1992) "Molecular Evolution of Proteins on Filamentous Phage." <i>Journal of Biological Chemistry</i> 267(23): 16007-16010.
19	MARKS ET AL. (1993) "Human Antibody Fragments Specific for Human Blood Group Antigens from a Phage Display Library." <i>BioTechnology</i> 11(10): 1145-1149.
20	MICHAEL ET AL. (1994) "Strategies to achieve targeted gene delivery via the receptor-mediated endocytosis pathway." <i>Gene Therapy</i> 1(4): 223-232.
21	NISSIM ET AL. (1994) "Antibody fragments from a 'single pot' phage display library as immunochemical reagents." <i>The EMBO Journal</i> 13(3): 692-698.
22	PEREIRA ET AL. (1997) "A model system for detection and isolation of a tumor cell surface antigen using antibody phage display." <i>Journal of Immunological Methods</i> 203(1): 11-24
23	SHEETS ET AL. (1998) "Efficient construction of a large nonimmune phage antibody library." <i>Proceedings of the National Academy of Sciences</i> 95(11): 6157-6162.
24	SOMIA ET AL. (1995) "Generation of targeted retroviral vectors by using single-chain variable fragment: An approach to <i>in vivo</i> gene delivery." <i>Proceedings of the National Academy of Sciences</i> 92(16): 7570-7574.
25	STANCOVSKI ET AL. (1991) "Mechanistic aspects of the opposing effects of monoclonal antibodies to the ERBB2 receptor on tumor growth." <i>Proceedings of the National Academy of Sciences</i> 88(19): 8691-8698.
26	STAUSBØL-GRØN ET AL. (1996) "A model phage display subtraction method with potential for analysis of differential gene expression." <i>FEBS Letters</i> 391: 71-75.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



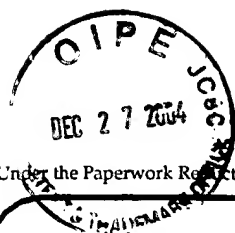
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<b>Substitute for form 1449A-B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)	<b>Complete if Known</b>	
	Application Number	09/250,056
	Filing Date	February 12, 1999
	First Named Inventor	James D. Marks
	Group Art Unit	1642
	Examiner Name	Larry R. Helms
	Attorney Docket Number	407J-895030US
	Date Submitted	December 21, 2004

27	ULLRICH ET AL. (1990) "Signal Transduction by Receptors with Tyrosine Kinase Activity." <i>Cell</i> 61(2): 203-212.	
28	VAUGHAN ET AL. (1996) "Human Antibodies with Sub-nanomolar Affinities Isolated from a Large Non-immunized Phage Display Library." <i>Nature Biotechnology</i> 14: 309-314.	
29	WATKINS ET AL. (1997) "The 'adenobody' approach to viral targeting: specific and enhanced adenoviral gene delivery." <i>Gene Therapy</i> 4(10): 1004-1012.	
30	WATTERS ET AL. (1997) "An optimized method for cell-based phage display panning." <i>Immunotechnology</i> 3: 21-29.	
31	YARDEN (1990) "Agonistic antibodies stimulate the kinase encoded by the <i>neu</i> protooncogene in living cells but the oncogenic mutant is constitutively active." <i>Proceedings of the National Academy of Sciences</i> 87(7): 2569-2573.	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



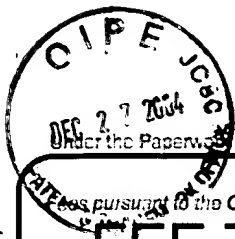
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	<b>Application Number</b>	09/250,056	
	<b>Filing Date</b>	February 12, 1999	
	<b>First Named Inventor</b>	James D. Marks	
	<b>Group Art Unit</b>	1642	
	<b>Examiner Name</b>	Larry R. Helms	
<b>Total Number of Pages in This Submission</b>	7	<b>Attorney Docket Number</b>	407J-895030US

ENCLOSURES (check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment / Response	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	receipt acknowledgment postcard
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Small Entity Statement	
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> Request for Refund	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application	<b>Authorization to Charge Deposit Account</b> Please charge Deposit Account No. 50-0893 for any additional fees associated with this paper or during the pendency of this application, including any extensions of time for consideration of the documents enclosed.	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Angela P. Horne, Reg. No. 41,079, Quine Intellectual Property Law Group, P.C.
Signature	<i>Angela P. Horne, PhD</i>
Date	December 21, 2004

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below			
Typed or printed name	Deborah Berwick		
Signature	<i>Deborah Berwick</i>	Date	December 21, 2004



PTO/SB/17 (12-04)

Approved for use through 07/31/2008. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 461E).

# FEE TRANSMITTAL

## For FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

## Complete if Known

Application Number	09/250,056
Filing Date	February 12, 1999
First Named Inventor	James D. Marks
Examiner Name	Larry R. Helms
Art Unit	1642
Attorney Docket No.	407J-895030US

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☒ Other (please identify): Deposit Account

☒ Deposit Account Deposit Account Number: 50-0893 Deposit Account Name: Quine Intellectual Property Law Group, P.C.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayments of fee(s) ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

## FEE CALCULATION

## 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

## 2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims: \_\_\_\_\_ - 20 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_ Fee Paid (\$)

HP = highest number of total claims paid for, if greater than 20

Indep. Claims: \_\_\_\_\_ - 3 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_ Fee Paid (\$)

HP = highest number of independent claims paid for, if greater than 3

## 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	(\$)	Fee Paid (\$)
_____ - 100 = _____	_____ / 50 = _____	_____ (round up to a whole number)	x _____	_____

## 4. OTHER FEE(S)

Other: <u>Submission of Information Disclosure Statement</u>	Fees Paid (\$)
Other: _____	180.00

## SUBMITTED BY

Signature	<u>Angela P. Horne</u>	Registration No. (Attorney/Agent)	41,079	Telephone	
Name (Print/Type)	Angela P. Horne	Date	Dec. 21, 2004		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.